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PATENT
DOCKET NO. BSA-010.03

In re Application of: Babich, J.W., et al.

Application No: 10/756,793

Filed: January 13, 2004

For: Imaging Agents for Diagnosis of
Parkinson's Disease

Art Unit: 1625

Examiner: Not Yet Known

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on *July 7, 2004*


John Barretto

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Forms PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Under 35 U.S.C. §120, this application has the benefit of the filing date of U.S. Patent Application 10/352,764, filed January 28, 2003, now US Patent 6,677,454; and US Patent Application 09/790,320 filed February 22, 2001, now US Patent 6,515,131. Copies of references AA-CU listed on the Forms PTO-1449 were submitted to the Office in the parent applications; therefore, they are not required to be provided in this application.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed:

- ☒ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office Action** on the merits, or before the mailing of a **first Office Action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☐ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**
- ☐ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or
- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

STATEMENT

As required under 37 C.F.R. 1.97(e), Applicant(s), through the undersigned, hereby state either that **[check the appropriate space only if either (2) or (3) is checked on the previous page and the Statement is required]**:

- ☐ 1. Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application **not more than three months** prior to the filing of the Information Disclosure Statement; or
- ☐ 2. No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to **any**

individual designated in 37 C.F.R. 1.56(c) **more than three months** prior to the filing of the Information Disclosure Statement.

Respectfully submitted,



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Reg. No. 44,719

Form PTO-1449

**INFORMATION DISCLOSURE CITATION
IN AN APPLICATION**
(Use several sheets if necessary)

JUL 09 2004

Docket Number (Optional)
BSA-010.03 (20704-1002)

Application Number
10/756,793

Applicant
Babich, J.W et al.

Filing Date
January, 13, 2004

Group Art Unit
1625
U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER		DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	US 5,288,514	02/22/94	Ellman	427	2	09/14/92
	AB	US 5,362,899	11/08/94	Campbell	558	108	09/09/93
	AC	US 5,359,115	10/25/94	Campbell et al.	558	110	09/11/92
	AD	US 5,143,854	09/01/92	Pirring et al	436	518	03/07/90
	AE	US 5,480,971	01/02/96	Houghten et al.	530	328	06/09/94
	AF	US 5,440,016	08/08/95	Blondelle et al	530	330	06/18/93
	AG	US 5,919,934	01-2001	John et al	546	247	
	AH	US 6,171,576	01-2001	Meltzer et al.	424	1.65	
	AI	US 5,136,038	08-1992	Bodor	546	169	

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						YES	NO
	AJ	WO 91/07087	05/30/91	PCT			X
	AK	WO 93/09668	05/27/93	PCT			X
	AL	WO 92/10092	06/25/92	PCT			X
	AM	WO 94/08051	04/14/94	PCT			X
	AN	WO 93/20242	10/14/93	PCT			X
	AO	WO 98/37055	08/27/98	PCT			X
	AP	WO 01/83436 A2	11/08/01	PCT			X
	AQ	WO 01/98266	12-2001	PCT			
	AR	EP 0 200 211 A1	11/05/86	European Patent Application			X

OTHER DOCUMENTS*(Including Author, Title, Date, Pertinent Pages Etc.)*

AS	Innis et al.; "Single Photon Emission Computed Tomography Imaging of Monoamine Reuptake Sites in Primate Brain With [¹²³ I] CIT", European Journal of Pharmacology 200, 369-370, (1991)
AT	Kung et al.; "Imaging of Dopamine Transporters in Humans with Technetium-99m TRODAT-1", European Journal of Nuclear Medicine, 23 (11): 1527-1530, (1996)
AU	Dahl et al.; "Deletion Mapping of X-Linked Mixed Deafness (DFN3) Identifies A 265-525-kb Region Centromeric of DXS26", Am. J. Hum. Genet. 56: 999-1002, (1995)
AV	Valerio et al.; "Synthesis of Peptide analogues Using the Multipin Peptide Synthesis Method", Analytical Biochemistry 197: 168-177 (1991)

Form PTO-1449		Docket Number (Optional) BSA-010.03 (20704-1002)		Application Number 10/756,793	
INFORMATION DISCLOSURE CITATION IN AN APPLICATION <i>(Use several sheets if necessary)</i>		Applicant Babich, J.W et al.			
		Filing Date January, 13, 2004		Group Art Unit 1625	
	AW	Stoof et al.; "Leads for the Development of Neuroprotective Treatment in Parkinson's Disease and Brain Imaging Methods for Estimating Treatment Efficacy", European Journal Of Pharmacology 375: 75-86, (1999)			
	AX	Gallop et al.; "Application of Combinatorial Technologies to Drug Discovery. 1. Background and Peptide Combinatorial Libraries", Journal of Medicinal Chemistry, 37(9) : 1233-1251, (April 29, 1994)			
	AY	Berge et al.; "Pharmaceutical Salts", Journal of Pharmaceutical Sciences, 66(1): 1-19, (January 1977)			
	AZ	Ohlmeyer et al.; "Complex Synthetic Chemical Libraries Indexed with Molecular Togs", Proc. Natl. Acad. Sci., USA, 90: 10922-10926, (December 1993)			
	BA	Innis et al.; "Single Photon Emission Computed Tomographic Imaging Demonstrates Loss of Striatal Dopamine Transporters in Parkinson Disease", Proc. Natl. Acad. Sci., USA 90: 11965-11969, (December 1993)			
	BB	Kung et al.; "Synthesis of New Bis (Aminoethanethiol) (BAT) Derivatives: Possible Ligands for ^{99m} Tc Brain Imaging Agents", J. Med. Chem. 28: 1280-1284, (1985)			
	BC	Meltzer et al.; "Substituted 3-Phenyltropane Analogs of Cocaine: Synthesis, Inhibition of Binding at Cocaine Recognition Sites, and Positron Emission Tomography Imaging", J. Med. Chem. 36: 855-862, (1993)			
	BD	Carroll et al.; "Cocaine Receptor: Biochemical Characterization and Structure-Activity Relationships of Cocaine Analogues at the Dopamine Transporter", Journal of Medicinal Chemistry, 35(6): 969-981, (March 20, 1992)			
	BE	Meegalla et al.; "First Example of a ^{99m} Tc Complex as a Dopamine Transporter Imaging Agent", J. Am. Chem. Soc. 117: 11037-11038, (1995)			
	BF	Smith et al.; "Tuning Selectivity of Monoamine Transporter Inhibitors by the Stereochemistry of the Nitrogen Lone Pair", J. Am. Chem. Soc. 120: 9072-9073, 9 1998)			
	BG	Neumeyer et al.; "[¹²³ I]-2β-Carbomethoxy-3β-(4-iodophenyl) Tropane: High-Affinity SPECT Radiotracer of Monoamine Reuptake Sites in Brain", J. Med. Chem. 34 : 3144-3146, (1991)			
	BH	Hoepping et al.; "Synthesis and Biological Evaluation of Two Novel Dat-Binding Technetium Complexes Containing a Piperidine Based Analogue of Cocaine", Bioorganic & Medicinal Chemistry Letters, 9: 3211-3216, (1999)			
	BI	Gu et al.; "Stable Expression of Biogenic Amine Transporters Reveals Differences in Inhibitor Sensitivity, Kinetics, and Ion Dependence", The Journal of Biological Chemistry, 269 (10): 7124-7130, (1994)			
	BJ	Frost et al.; "Positron Emission Tomographic Imaging of the Dopamine Transporter with ¹¹ C -WIN 35,428 Reveals Marked Declines in Mild Parkinson's Disease", Annals of Neurology, 34: 423-431, (1993)			
	BK	Blaney and Dixon, "Receptor Modeling by Distance Geometry", Annual Reports in Medicinal Chemistry, 26:281-286, (1991)			
	BL	Meegalla et al.; "Synthesis and Characterization of Technetium-99m- Labeled Tropanes as Dopamine Transporter-Imaging Agent", J. Med. Chem. 40: 9-17, (1997)			
	BM	Hamilton and Steiner, "Immunophilins: Beyond Immunosuppression", Journal of Medicinal Chemistry, 41(26):5119-5143, (December 17, 1998)			

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		Filing Date January, 13, 2004		Group Art Unit 1625	
	BN	Luyt et al.; "An N ₂ S ₂ Bifunctional Chelator for Technetium-99m and Rhenium: Complexation, Conjugation, and Epimerization to a Single Isomer", Bioconjugate Chem. 10: 470-479, (1999)			
	BO	Hom and Katzenellenbogen; "Technetium-99m-Labeled Receptor-Specific Small-Molecule Radiopharmaceuticals: Recent Developments and Encouraging Results", Nuclear Medicine and Biology, 24: 485-498, (1997)			
	BP	Nicholson et al.; "The Synthesis and Characterization of [MCl ₃ (N=NC ₅ H ₄ NH) (HN=NC ₅ H ₄ N)] From [MO ₄] ⁻ (where M= Re, Tc) Organodiazenido, Organodiazene-Chelate Complexes. The X-ray Structure of [ReCl ₃ (N=NC ₅ H ₄ NH) (HN=NC ₅ H ₄ N)]", Inorganica Chimica Acta, 252: 421-426, (1996)			
	BQ	Rose et al.; "Synthesis and Characterization of Organohydrazino Complexes of Technetium, Rhenium, and Molybdenum with the {M(η ¹ -H _x NNR)(η ² -H ₂ NNR)} Core and Their Relationship to Radiolabeled Organohydrazine-Derivatized Chemotactic Peptides With Diagnostic Applications", Inorg. Chem. 37: 2701-2716, (1998)			
	BR	Fowler et al.; "Mapping Cocaine Binding Sites in Human and Baboon Brain In Vivo", Synapse, 4:371-377, (1989)			
	BS	Villemagne et al.; "Doses of GBR12909 That Suppress Cocaine Self-Administration in Non - Human Primates Substantially Occupy Dopamine Transporters as Measured by [11 C] WIN35,428 PET Scans", Synapse 32: 44-50, (1999)			
	BT	Shaya et al.; "In Vivo Imaging of Dopamine Reuptake Sites in the Primate Brain Using Single Photon Emission Computed Tomography (SPECT) and Iodine-123 Labeled RTI-55", Synapse 10: 169-172 (1992).			
	BU	Ilgin et al.; "PET Imaging of the Dopamine Transporter in Progressive Supranuclear Palsy and Parkinson's Disease", Neurology 52: 1221-1226, (1999)			
	BV	Kaufman and Madras; "Distribution of Cocaine Recognition Sites in Monkey Brain: II. EX Vivo Autoradiography With [³ H] CFT and [¹²⁵ I] RTI-55", Synapse 12: 99-111, (1992).			
	BW	Jacobs and Fodor, "Combinatorial Chemistry- Applications of Light-directed Chemical Synthesis", TIBTECH. 12:19-26, (January 1994).			
	BX	Chen et al.; "Analogous" Organic Synthesis of Small Compound Libraries: Validation of Combinatorial Chemistry in Small-Molecule Synthesis", J. Am. Chem. Soc. 116: 2661-2662, (1994)			
	BY	Kerr et al.; "Encoded Combinatorial Peptide Libraries Containing Non- Natural Amino Acids", J. Am. Chem. Soc. 115: 2529-2531, (1993)			
	BZ	Kozikowski et al.; "Chemistry and Pharmacology of the Piperidine-Based Analogues of Cocaine. Identification of Potent DAT Inhibitors Lacking the Propane Skeleton", J. Med. Chem. 41: 1962-1969, (1998)			
	CA	Patane et al.; "Selective α-1A Adrenergic Receptor Antagonists. Effects of Pharmacophore Regio- and Stereochemistry on Potency and Selectivity", Bioorganic and Medicinal Chemistry Letters 8:2595-2500, (1998)			
	CB	Yung et al.; "In Vivo Dopamine Transporter Sites Imaging in Human Using [c-11] WIN 35,428 Positron Emission Tomography (pet)", The Journal of Nuclear Medicine, 34(5): 197P(Abstract book), (May 1993)			
	CC	Spies et al.; "Neutral Oxorhenium (v) Complexes with Tridentate Dithiolates and Monodentate Alkane- or Arene-thiolate Coligands", J. Chem Soc. Dalton Trans.; No 13, pp.2277-2280, (July 7 th , 1995)			
	CD	Needels et al.; "Generation and Screening of an Oligonucleotide-encoded synthetic Peptide Library", Proc. Natl. Acad. Sci. USA 90: 10700-10704, (November 1993)			

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		Filing Date January, 13, 2004		Group Art Unit 1625	
	CE	Brenner and Lerner, "Encoded Combinatorial Chemistry", Proc. Natl. Acad. Sci. USA 89: 5381-5383, (June 1992)			
	CF	Bray et al.; " Gas Phase Cleavage of Peptides from a Solid Support with Ammonia Vapour. Application in Simultaneous Multiple Peptide Synthesis", tetrahedron Letters 32(43): 6163-6166, (1991)			
	CG	Bray et al.; " The Simultaneous Multiple Production of Solution Phase Peptides; Assessment of the Geysen Method of Symultaneous Peptide Synthesis", Tetrahedron Letters, 31 (40): 5811-5814, (September 24, 1990)			
	CH	Pátek and Lebl, " Safety-Catch anchoring Linkage for Synthesis of Peptide Amides by Boc/Fmoc Strategy", Tetrahedron Letters, 32 (31): 3891-3894 (July 29, 1991)			
	CI	Mitra-Kirtley; " Determination of the Nitrogen Chemical Structures in Petroleum Asphaltenes Using XANES Spectroscopy", J. Am Chem. Soc. 115(1): 252-258, (January 13, 1993)			
	CJ	Geysen et al.; " Use of Peptide Synthesis to Probe Viral Antigens for Epitopes to a Resolution of a Single Amino Acid", Proc. Natl. Acad. Sci. USA 81(13): 3998-4002, (July 1984)			
	CK	Houghten A. Richard, " General Method for the Rapid Solid-Phase Synthesis of Large Numbers of Peptides: Specificity of Antigen-Antibody Interaction at the Level of Individual Amino Acids", Proc. Natl. Acad. Sci. , 82: 5131-5135, (August 1985)			
	CL	Hui et al.; " Analysis of the Quantitative Structure Activity Relationship of Technetium-99m-Labeled Diaminedithiol (DADT) and Propyleneamineoxine (PAO) Brain Blood Flow Analogues", Appl. Radiat. Isot. (International Journal of Radiation Applications: Part A). 42(6): 503-508, (1991)			
	CM	Fodor et al.; " Light-Directed, Spatially Addressable Parallel Chemical Synthesis", Science, 251: 767-773, (February 15, 1991)			
	CN	Galli et al.; " Sodium- Dependent Norepinephrine-Induced Currents in Norepinephrine-Transporter-Transfected Hek-293 Cells Blocked by Cocaine and Antidepressants", The Journal of Experimental Biology, 198: 2197-2212, (1995)			
	CO	Warren et al.; " New Iodinated Phenyl Fatty Acids For Imaging Myocardial Metabolism", The Journal of Nuclear Medicine 27(6): abstract no. 258, (June 1986)			
	CP	Mozley et al.; " Dosimetry of an Iodine-123-Labeled Tropane to Image Dopamine Transporters", J. Nucl. Med. , 37(1): 151-159, (January 1996)			
	CQ	Nestler et al.; " A General Method for Molecular Tagging of Encoded Combinatorial Chemistry Libraries", J. Org. Chem. 59(17): 4723-4724, (august 26, 1994)			
	CR	Burbaum et al.; "A Paradigm for Drug Discovery Employing Encoded Combinatorial Libraries", Proc. Natl. Acad. Sci. USA, 92: 6027-6031, (June 1995)			
	CS	Efange et al.; " Synthesis and Biodistribution of 99 mTc -Labeled Piperidiny bis (Aminoethanethiol) Complexes: Potential Brain Perfusion Imaging Agents for Single Photon Emission Computed Tomography", CA 108: 167266 (1988)			
	CT	Partial International Search Report Mailed on Marcyh 14, 2002			
	CU	International Search Report Completed on June 20, 2002 and Mailed July 7, 2002			
EXAMINER				DATE CONSIDERED	
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.					